REMARKS

The final Office Action sent June 08, 2009, has been received and reviewed. All claims have been rejected. The application is to be amended as previously set forth. Support for the amendments to claims 1 and 6 are found throughout the Specification and, for example, at paragraphs **[0032]-[0035]**, and Example 1, Table 3. New claim 25 is supported throughout the Specification and, for example, at paragraph **[0043]**. Support for new claim 29 is found throughout the Specification and, for example, at paragraphs **[0044]**, **[0049]**, and Example 1, Tables 1 and 3. Other amendments maintain antecedent basis in light of the amendments to the base claims. No new matter has been added.

Reconsideration is respectfully requested.

A. Claim Objections

Claims 22-24 have been objected to as assertedly being in improper form. Claim 22 has been amended rendering the objection moot.

Applicants respectfully request that the objection to claims 22-24 be withdrawn.

B. 35 U.S.C. § 112

Claims 1-20 and 22-24 have been rejected under 35 U.S.C. § 112, first paragraph, for assertedly failing to comply with the written description requirement. Claims 2-4, 7, and 12-20 have been cancelled rendering the rejection of these claims moot. As to the remaining claims, the rejection is traversed, but is also overcome by the instant clarifying amendments.

The Office appears to assert that, since Example 1 relates to a formulation including compound 22c and spinosad, there is no support for the dosage or efficacy of a formulation including other mixtures of azole pesticides (*i.e.* compounds of formula (I)) and one or more spinosyns. *Office Action of June 8, 2009*, pp. 2-3. Applicants respectfully disagree and assert that the disclosure is not so limited. In particular, it is noted that Applicants need not describe all actual embodiments and, further, that the teachings of the application are not limited to its

preferred embodiment. Rather, the specification must describe the invention in sufficient detail to show that the inventor had possession of the claimed invention. *See*, M.P.E.P. § 2163.

In the instant application, the as-filed specification discloses treatment of an animal with a dose "of from 0.1 to 100 and in particular from 1 to 40 mg/kg bodyweight of the compound of formula (I) and a dose from 0.1 to 100 and in particular 1 to 40 and most preferably less than 30 mg/kg bodyweight of the spinosyn compound(s). These dosages have been proven to be effective." *As-filed specification*, paragraph **[0044]**. Therefore, the claimed invention is not limited to compound 22c and spinosad, as asserted by the Office. Instead, Example 1 teaches a representative formulation of the invention and clearly describes distinguishing identifying characteristics. Thus, the invention is disclosed in sufficient detail that person of ordinary skill in the art would have understood the applicants to be in possession of the claimed invention. However, in order to further clarify and expedite prosecution, applicants have amended each of claims 1 and 6, to include a formulation comprising spinosad and compound 22c, rendering the rejection moot.

The rejections under 35 U.S.C. § 112, first paragraph, should be withdrawn.

C. 35 U.S.C. § 103(a)

Claims 1-20 and 22-24 have been rejected under 35 U.S.C. § 103(a) for assertedly being obvious in view of European Patent No. 0 412 849 A to Willis et al. ("Willis") and International Publication No. WO 01/11963 A1 to Snyder ("Snyder"). Claims 2-4, 7, and 12-20 have been cancelled rendering the rejection as to these claims moot. As to the remaining claims, the rejection is traversed, but is also overcome by the instant clarifying amendments.

The obviousness rejection is improper because the applied references, separately or in combination, do not teach or suggest all of the claim limitations. Additionally, the claims are not obvious because applicants have shown that the claimed invention has achieved new and unexpected results.

Claim 1 is nonobvious over the combination of cited references because Willis and Snyder, separately or in combination, do not teach or suggest a formulation including 5-chloro-1-

(2,6-dichloro-4-trifluoromethylphenyl)-4-(4,5-dicyano-1H-imidazol-2-yl)-3-methyl-1-H pyrazole ("compound 22c") or a salt thereof, *in combination with* spinosad. Although the cited references separated disclose the individual compounds, they do not disclose the new combination as claimed. Moreover, a statement that modifications of the prior art to meet the claimed invention would have been "well within the ordinary skill of the art at the time the claimed invention was made" because the references relied upon teach that all aspects of the claimed invention were individually known in the art *is not sufficient to establish a prima facie case of obviousness.* M.P.E.P. § 2143.01(IV) (emphasis added).

Further, even assuming, *arguendo*, Willis and Snyder disclosed a formulation including compound 22c and spinosad; nevertheless, the applied references do not teach or suggest a formulation "capable of achieving an efficacy of at least 90% in controlling flea and tick infestations in an animal for at least 7 days after administration" as presently claimed. Willis fails to disclose any teaching of the efficacy of the formulation in controlling tick infestations, in an animal, at any time point. Furthermore, Snyder teaches that the spinosyns lose efficacy against ticks in animals, within 9 days, at a significantly higher dose. *Snyder*, Table 3.

Additionally, even if a *prima facie* case of obviousness were established in the instant case, which applicants do not concede, applicants have rebutted such a *prima facie* case by showing unexpected results. *See*, M.P.E.P. § 2144.05(III). In the instant application the Examples describe that persistent activity against fleas and ticks is achieved by the combination of 5-chloro-1-(2,6-dichloro-4-trifluoromethylphenyl)-4-(4,5-dicyano-1H-imidazol-2-yl)-3 methyl -1-H pyrazole or a salt thereof, and spinosad. Conversely, spinosyns by themselves are known to lose effectiveness against ticks 5-9 days after the treatment. *As-filed specification*, Example 3, Table 6; *Snyder*, p. 13, Table 3. The Snyder study, and applicants study, each show that the efficacy of a 50 mg/kg spinosyn dosage is insufficient to prevent reinfestation of the animal 5-9 days after the initial treatment. *Id.* Absent impermissible hindsight, the Examiner has failed to identify anything in the art of record that would have provided a reason for a person of ordinary skill in the art to reasonably expect that the efficacy of the spinosyns may be increased by combination with an azole pesticide (*i.e.* compound 22c). The formulation of claim 1 achieves

the unexpected result of improved efficacy (95.7%) against ticks for at least 7 days after treatment, while at a lower dosage. *As-filed specification*, Example 1, Table 3. As such, it is respectfully submitted that the claimed formulation would not have been obvious to a person of ordinary skill at the time of the invention.

Each of claims 3 and 4 depends from claim 1 and, therefore, is also believed to be nonobvious over the cited art.

Claim 6 is nonobvious over the combination of cited references because Willis and Snyder, separately or in combination, do not teach or suggest a method of controlling an ectoparasite infestation in an animal using a formulation as recited in claim 1. As discussed previously, although Willis and Snyder disclose the individual components of the formulation, it would not have been obvious to combine them in the manner asserted, at least, because the combination achieves unexpected results.

Additionally, although Willis discloses that azole pesticides may be utilized against ectoparasites, it does not teach a method of administering the azole pesticides as presently claimed. Rather, at most, Willis describes administering a single dose of compound 22c to control *an endoparasitic* infestation (*i.e.* gastrointestinal nematodes) in an animal. *Willis*, p. 25. lines 30-37. Further, Willis fails to teach or suggest achieving a persistent efficacy of at least 90% in killing fleas *and ticks* for at least 7 days after the treatment. Similarly, Snyder does not disclose the claimed method. Instead, Snyder teaches that a single dose of spinosyns, at a significantly higher dosage (*i.e.* 50 mg/kg), only has a 67.8% efficacy at 9 days. *Snyder*, p. 13, Table 3. Therefore, Willis and Snyder do not teach or suggest all of the elements of claim 6.

Each of claims 7-11 and 22-24 depends, directly or indirectly, from claim 6 and, therefore, is also believed to be nonobvious over the cited references.

For the foregoing reasons, the 35 U.S.C. § 103(a) obviousness rejection should be withdrawn and the claims allowed.

D. New claims

Applicants respectfully submit that new claims 25-28 are allowable because Willis and Snyder, separately or in combination, do not teach or suggest a formulation comprising azole pesticides and one or more spinosyns in a ratio from about 1:10 to about 10:1. Specifically, neither Willis nor Snyder discloses a formulation including spinosyns and azole pesticides. Even if, as the Office suggests, one could combine the separate elements of claim 25 in the references cited by the Office, this does not mean that their combination is obvious. As discussed previously, the combination is nonobvious, at least, because it achieves unexpected results. Furthermore, applicants submit that the formulation of claim 25 is additionally nonobvious because there would have been no reasonable expectation of success.

In particular, since neither Willis nor Snyder teaches or suggests combining one or more azole pesticide and one or more spinosyn, the cited references, necessarily, do not teach or suggest the ratio's of the individual components in the asserted combined formulation. Applicants submit that the subject matter of claim 25 would not have been obvious to one of ordinary skill in view of the number of unpredictable, possible combinations of elements and ratios from the applied references. The Office has failed to provide any reasoning that a person of ordinary skill in the art would have found it obvious to utilize any finite number of compounds, in specific ratios, with any degree of predictability.

Each of new claims 29-31 is allowable for substantially the same reasons as set forth for claim 25 above. Furthermore, claim 29 is additionally allowable because neither Willis nor Snyder teaches or suggests a method including administering a first dosage and subsequently administering a reduced dosage. In contrast, Snyder teaches away from a serial administration because it is, instead, directed to a "single dose oral formulation." *Snyder*, p. 3. Likewise, Willis only discloses administering a single dose of compound 22c to control endoparacites in an animal. *Willis*, p. 25, lines 30-35. Therefore, Willis and Snyder do not teach or suggest all of the limitations of claims 25-31.

For the foregoing reasons, applicants submit that each of claims 1, 5-11, and 22-31 are in condition for allowance. If, however, questions remain after consideration of the foregoing, the Office is kindly requested to contact applicants' undersigned attorney.

Respectfully submitted,

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Date: September 8, 2009